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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/612,532  | 07/01/2003  | Jon S. Wilson        | 3600/252            | 5249             |
| 1912  | 7590        | 10/12/2006           | EXAMINER            |                  |
| AMSTER, ROTHSTEIN & EBENSTEIN LLP<br>90 PARK AVENUE<br>NEW YORK, NY 10016 |             |                      | THANH, LOAN H       |                  |
|   |             |                      | ART UNIT            | PAPER NUMBER     |
|   |             |                      | 3763                |                  |

DATE MAILED: 10/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                        |                     |  |
|------------------------------|------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |  |
|                              | 10/612,532             | WILSON ET AL.       |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |  |
|                              | LoAn H. Thanh          | 3763                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 01 July 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>03/10/04, 03/11/04, 02/14/05</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Information Disclosure Statement***

The information disclosure statement (IDS) submitted on 03/10/04, 03/11/04 & 02/14/05 were filed before the first office action on the merits. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the examiner is considering the information disclosure statement.

### ***Specification***

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: Applicant does not have support for inserting the proximal portion of the multi-lumen catheter into the catheterized area. However, applicant does have support for inserting the distal portion of the multi-lumen catheter.

### ***Claim Rejections - 35 USC § 112***

Claims 1-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 7, 12 and 16 are vague and indefinite because it appears that applicant has reversed and inter changeably used "proximal" and "distal" language. Applicant is to make the correct changes so the claims are clear. Applicant has support for routing the distal portion of the catheter tube through the tunnel but it is unclear how the proximal portion of the catheter tube is inserted also.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 16 is rejected under 35 U.S.C. 102(b) as being anticipated by Mahurkar et al. ( US 5,221,255) .

Mahurkar et al. discloses a method of inserting a multi-lumen catheter comprising the steps of making an insertion incision , inserting a distal portion of the multi-lumen catheter tube into the catheterized area , creating a subcutaneous tunnel , routing the distal portion of the multi-lumen catheter tube and attaching the proximal portion of the catheter tube to a device. See figures 1-7, 13-44. See col. 9 lines 3-35.

Claims 1-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Abrahamson ( WO 97/22374).

Abrahamson discloses a multi-lumen catheter used in combination with the method steps comprising making an insertion , inserting the distal portion of the multi-lumen catheter tube and routing the distal portion of through the subcutaneous tunnel and attaching the first end of the detachable extension tube. The method steps are further disclosed in US 5,403,291, which was incorporated. See page 9 ,lines 17. See figures 7-17. Abrahamson discloses extension tubes 18, 20 connected to connectors 37,38 which are in fluid communication with catheter tube 12 having at least

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2 lumen 24,26. Clamps 42, 44 are for engaging and disengaging extension tube to prevent or allow fluid flow. The gripping portion of the tubes are shown at the proximal portions of the extension tubes by the luer connectors 43,45. See columns 9-18. The broad language of the "indicator" in claim 12, is interpreted by the Examiner with reference to figures 9-10. Abrahamson shows the d-shaped channel and the d-shaped lumen for which the cannula/connector 36-37 is inserted into. Thus, this is an indicator that would require the user to match the d-shaped tubes into the d-shaped lumen to connect.

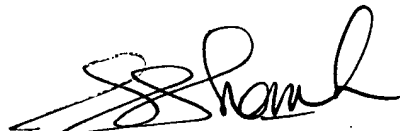
### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LoAn H. Thanh whose telephone number is (571) 272-4966. The examiner can normally be reached on Mon. - Fri. (First Friday off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on (571) 272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



LoAn H. Thanh  
Primary Examiner  
Art Unit 3763

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